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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,890	08/28/2000	Oliver Brustle	V0S-012	7106

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
05/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/581,890	BRUSTLE, OLIVER	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *106-114,116-124,126-133 and 135-139* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *106-114,116-124,126-133 and 135-139* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed February 15, 2007 (hereinafter referred to as "the response") has been entered. Claims 106, 118, 127, 128, 130-133, 135, and 136 have been amended. Claims 115, 125, and 134 have been cancelled and Claims 137-139 have been newly added.

Accordingly, Claims 106-114, 116-124, 126-133, and 135-139 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 15, 2007 has been entered.

The rejection of Claims 115, 125, and 134 under 35 U.S.C. 112, first paragraph, for lack of enablement over the full scope is withdrawn in view of the cancellation of these claims.

The rejection of Claims 106-136 under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,980,885 (Weiss et al., 1999; filed June 7, 1995) is withdrawn in view of the newly added claim limitations reciting "regional-identity unrestricted, pluripotent cell composition". However, the newly added limitations are rejected under 35 U.S.C. 112, first paragraph, for new matter, and under 35 U.S.C. 112, second paragraph, for indefiniteness.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 106-114, 116-124, 126-133, and 135-139 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claims and newly added claims include new matter.

MPEP 2163.03 provides that an amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989). Applicants should specifically point out the support for any amendments made to the claims. MPEP 2163 states that new or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) and *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

The claims have been amended so that they now recite the limitation "an isolated, non-tumorigenic, regional-identity unrestricted, pluripotent cell composition." The cell composition is said to consist essentially of "embryonic stem cell-derived neural precursor cells, and neuronal or glial cells derived from embryonic stem cell-derived neural precursor cells" or "embryonic stem cell-derived glial precursor cells, and glial cells derived from the embryonic stem cell-derived glial precursor cells." However, the specification fails to describe or contemplate a "regional-identity unrestricted, pluripotent cell composition" as now claimed. The specification makes no mention of a "regional-identity

unrestricted" cell composition and one of skill in the art would not be apprised of the meaning of the terminology. Furthermore, the use of the term "pluripotent" in the context of the claims is contrary to the meaning accepted in the art. As used in the art, the term "pluripotent" clearly and unambiguously refers to cells that have the ability to give rise to cell types that develop from the three germ layers (mesoderm, endoderm, and ectoderm) (see Stem Cells: Scientific Progress and Future Research Directions, June 2001, at pages ES-2 and F-8). The reference further discloses that the only known sources of pluripotent cells are those isolated and cultured from early embryos (ES cells) and from fetal tissue destined to be part of the gonads (EG cells). The reference further discloses, at pages ES-3 and F-8, that progenitor or precursor cells are partially differentiated cells that give rise to differentiated cells. Thus, **pluripotent** cells are readily distinguished in the art from **multipotent** cells. There is no evidence that the claimed cell compositions comprise a single pluripotent cell. Moreover, the specification provides no description of a "regional-identity unrestricted, pluripotent cell composition" as now claimed. Except to say that the limitation is intrinsically supported throughout the specification, Applicants have not pointed to any support in the as-filed specification for the newly added claim limitation. The Examiner has reviewed the specification and finds no support in the as-filed specification for such a cell composition. Thus, the as-filed specification does not contemplate or describe the cell composition as presently recited in the claims.

Thus, the amended claims and newly added claims include new matter.

At page 9 of the response, Applicants assert that the "pluripotent" nature of embryonic stem-cell derived neural precursors, and neuronal or glial cells derived from the embryonic stem-cell-derived neural precursor cells is described throughout the application as filed. Applicants further assert that the well-known and commonly accepted definition of pluripotent is defined in Applicants' specification as "[p]recursor cells which have the potential to differentiate into many different .... mature cell types." No support is offered for this assertion and the assertion is contrary to the art-recognized meaning of "pluripotent" as discussed above. Given the art-recognized definition of "pluripotent", neural precursor

cells, glial precursor cells, and terminally-differentiated neurons and glial cells do not constitute **pluripotent** cell types.

At page 10 of the response, with regard to the "regional-identity unrestricted" nature of the claimed cell compositions, Applicants assert that there is no *ipsis verbis* requirement for written description and that the newly added claim limitation may be supported in the specification through express, implicit or inherent disclosure. Applicants provide no further comment on how the specification provides express, implicit or inherent disclosure of "regional-identity unrestricted" cell compositions or what the limitation means.

At page 10 of the response, Applicants assert that the regional-identity unrestricted nature of the claimed cell compositions would be understood by one of skill in the art as intrinsically or inherently present in the claimed cell compositions. No support is offered for this assertion.

Enablement

Pharmaceutical Compositions

Claims 137-139 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in the Office Actions of 4/21/04, 12/2/05, and 8/14/06, as applied to Claim 97, because the specification, while being enabling for pharmaceutical compositions comprising neuronal cells, does not reasonably provide enablement for pharmaceutical compositions comprising glial cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 137-139 are directed to a pharmaceutical composition. The claims cover glial cell compositions.

Insofar as the claims continue to cover glial cell compositions as pharmaceutical compositions, the claims are rejected for lack of enablement. As noted below, and in the prior Office Action mailed 12/2/05, pharmaceutical compositions comprising neuronal cells are considered to be enabled.

At page 11 of the response, with regard to the rejection of Claims 115, 125, and 134 for lack of an enabling disclosure for producing a therapeutic effect upon transplantation of the claimed cell compositions (i.e., the intended use of the claimed pharmaceutical compositions), Applicant asserts that Example 4 provides a therapeutic use for transplanting oligodendroglial/astrocytic precursors into myelin-deficient rats for the purpose of myelin regeneration. However, there is nothing in Example 4 that points to a therapeutic outcome and Applicant provides no support for the assertion that Example 4 provides a therapeutic use. Although donor mouse cells were detected in the rat brain following embryonic transplantation, no therapeutic effect was demonstrated. Applicants assert that the remyelination would be considered therapeutic. No support is offered for this assertion.

The rejection of Claims 46, 86, and 99 under 35 U.S.C. 112, first paragraph, for failing to provide an enabling disclosure for a pharmaceutical use of the claimed invention, was withdrawn in view of Applicant's arguments relating to Example 5.2, as set forth at pages 14-16 of the response of October 22, 2004. The Examiner acknowledges that transplantation of mouse ES cell-derived neural cell compositions into adult rat brain with ibotenic acid-induced striatal lesions resulted in reduced amphetamine-induced rotational behavior. However, these cell compositions were neuronal cell compositions, not glial cell compositions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 106-114, 116-124, 126-133, and 135-139 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 106-114, 116-124, 126-133, and 135-139 are indefinite in their recitation of "regional-identity unrestricted" and "pluripotent" because the specification does not define "regional-identity unrestricted" or "pluripotent". Furthermore, the specification does not provide implicit support for "regional-identity unrestricted" and any physical or functional properties intended to be associated with said "regional-identity unrestricted" nature. Furthermore, the newly added limitations of "regional-identity unrestricted" and "pluripotent" is inconsistent with the body of the claim which does not include the presences of a pluripotent cell type. On the contrary, the cells present in the claimed compositions are either neural precursor cells, glial precursor cells, or terminally-differentiated neurons or glial cells.

Conclusion

No claims are allowable.

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information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER